California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Robert Graul, RPh, Chair
Robert Swart, PharmD
Shirley Wheat, Public Member
Andrea Zinder, Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT AND ACTION

Report of the Legislation and Regulation Committee Meeting of January 7, 2009

C. SUMMARY OF THE LEGISLATION AND REGULATION COMMITTEE MEETING HELD ON JANUARY 7, 2009

Attachment C-1

Attachment C-1 contains the meeting summary of the Legislation and Regulation Committee Meeting of January 7, 2009.

D. SECOND QUARTERLY REPORT ON LEGISLATION AND REGULATION COMMITTEE GOALS FOR 2008/09

Attachment D-1

Attachment D-1 contains the second quarter's report of the Legislation and Regulation Committee for 2008/09.

Attachment C-1

SUMMARY OF THE LEGISLATION AND REGULATION COMMITTEE MEETING HELD ON JANUARY 7, 2009

(Text follows next page)

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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES

DATE: January 7, 2009

LOCATION: Los Angeles International Airport
Samuel Greenberg Board Meeting Room
1 World Way
Los Angeles, CA 90045

BOARD MEMBERS PRESENT:
Robert Graul, RPh, Chairperson
Andrea Zinder, Public Member, Chairperson
Robert Swart, PharmD

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Tessa Fraga, Administrative Analyst
Tina Thomas, Enforcement Analyst

Chairperson Graul called the meeting to order at 1:07 p.m.

Regulation Report

1. Board Approved Regulation – Undergoing Administrative Review

Amend Section 1760 – Disciplinary Guidelines

Chairperson Graul provided a brief status update on the pending regulation change. At the April 2008 board meeting, the board voted to adopt a regulation change to amend Title 16 CCR 1760 – Disciplinary Guidelines. After receiving additional clarifying comments from counsel, board staff submitted the completed rulemaking to the Department for review and approval in September 2008. While the department did approve this regulation, State and Consumer Services Agency is concerned about the optional language relating to automatic revocation when a probationer fails to submit

cost recovery as mandated. As a result it is being brought back to the board for further consideration.

Executive Officer Herold provided a staff recommendation that the committee consider removing the one "optional term" to allow the board to continue to pursue the remaining changes of the Disciplinary Guidelines.

MOTION: Support to move forward with a 15-day notice as recommended,

M/S: RS/AZ

SUPPORT: 3 OPPOSE: 0 ABSTAIN: 0

2. Board Approved Regulations – Previously Noticed (Not for discussion at this meeting)

Chairperson Graul indicated that these items are not for discussion for the committee.

Chairperson Graul briefly discussed the two changes by title only.

a. Proposed Repeal of 16 CCR §§ 1716.1 and 1716.2 and Amendment to 16 CCR § 1751-1751.8 and Adoption of 16 CCR §§1735-1735.8

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

The 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing. The subcommittee will be providing recommendations for consideration and action by the board at the January 2009 Board Meeting.

b. Proposed Amendment to 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course.

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on their discussion and work, the subcommittee recommended to the board that it vote to create a program similar to the program used by the Medical Board. This proposal

would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

The board determined the requirements as necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional eight hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). If after the 15-day public comment period, no adverse comments are received, the board authorized the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

The 15-day comment period is over and no additional comments were received. Board staff will begin compiling the rulemaking and will submit it to the department during the first quarter of 2009.

3. Board Approved Regulations – Awaiting Notice

Chairperson Graul provided an update on board approved regulations that are awaiting notice.

a. Proposed Amendment to 16 CCR §1715 and 16 CCR §1784 - Section 100 Changes to Update the Self Assessment Forms for Pharmacies and Wholesalers

Section 1715 establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law. Section 1784 establishes the requirement for the designated representative-in-charge of a licensed wholesaler to complete a self-assessment form to ensure

compliance with pharmacy law. These self-assessment forms are designed to assist pharmacies and wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the pharmacy inspection process more meaningful and educational and provide relevant information to pharmacies and their PIC.

Chairperson Graul noted that staff will compile the section 100 regulation change package in the first quarter of 2009.

b. Proposed Addition to 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

Chairperson Graul advised that a copy of the draft language and form is provided, however board staff do not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

c. Proposed Adoption of 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies and was approved at the July 2007 Board Meeting. The board voted to move this proposal.

Chairperson Graul advised that a copy of the language as approved by the board was provided in the meeting materials.

d. Proposed Amendment to 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §§1721 and 1723.1 which would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Chairperson Graul advised that a copy of the language as approved by the board was provided in the meeting materials.

4. Proposed Regulation Language for Board Discussion and Possible Action

Chairperson Graul advised that these items were previously discussed during the meeting as they were included on the agenda twice.

5. Regulations Under Development

a. Proposed Amendment to 16 CCR §1780 – Update the USP Standards Reference Material

Chairperson Graul provided a brief synopsis of the proposed change to CCR §1780, which sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Chairperson Graul highlighted that because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.
President Schell and Committee Chairperson Bob Graul are serving on the subcommittee and will be working with board staff and industry. Chairperson Graul requested volunteers to work with the subcommittee to address any potential concerns. Kaiser, California Society of Health-Systems Pharmacist and Western Medical Center - Santa Monica will have a representative serve on the subcommittee. Ms. Herold

indicated that she will also contact Healthcare Distribution Management Association for volunteers.

Chairperson Graul requested that board staff review the Pharmacy Law book for additional references in advance of the first subcommittee meeting.

b. Proposed Amendment to 16 CCR §1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member's term is generally about eight years.

Legislative Report

At the request of the Chairperson, Ms. Herold provided an overview of the Legislative Process.

The two year Legislative cycle began in December 2008. About one-third of the representatives are new. The board works hard to keep pharmacy law current. Beginning in December 2008, a special session was called to deal with the budget crisis. To date, this special session has not yielded any results. Legislatively all items will resolve around budget issues as they work to find a solution. Ms. Herold provided highlighted key dates on the legislative calendar including the February 27, 2009 bill submission deadline. All bills are subject to review by, at minimum, a policy committee and, if appropriate, a fiscal committee. All bills must be passed out of the house of origin by June 5, 2009. All bills must be passed by the second house by September 11 to move to the Governor. If the bill is enacted, unless otherwise specified, the bill will go into effect on January 1, 2010.

Ms. Herold also shared that bills which don't make it out of the house of origin by the deadline established can become a two year bill.

1. Legislation Sponsored by the Board of Pharmacy Omnibus Provisions from 2008

Chairperson Graul indicated that at the October 2008 Board Meeting, the board voted to pursue all omnibus provisions vetoed in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor.

These omnibus provisions were categorized into four types of changes:

1. Use of mobile pharmacies.
2. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.
3. General omnibus provisions.
4. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.

Public Comments:

Clarification was requested on the costs to implement these provisions.

Ms. Herold responded that the cost would be negligible as the majority of the changes are noncontroversial and nonsubstantive.

Dr. Swart sought clarification about the changes to B&PC 4062 and 4110 which would allow for the use of mobile pharmacy in the event a pharmacist was undergoing a remodel. Ms. Sodgergren advised the committee that this change is not reflected as the Senate Business and Professions Committee, the author of the omnibus bill, stated that the committee will again author the omnibus bill but will not allow for any changes to the provisions contained within SB 1779.

a. Omnibus Provisions for 2009

Chairperson Graul also highlighted the omnibus provision for 2009. At the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions.

Add Section 4146 – Disposal of Returned Sharps by a Pharmacy
This section needs to be added to allow a pharmacy to accept returned sharps containers from consumers for disposal.

Add Section 4013 – Subscriber Alert
This section needs to be added to require all board licensed facilities to join the board's e-mail notification list.

Amend Section 4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
This section requires amendment to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state.

Amend Section 4401 – Pharmacists: Biennial Renewal
This section needs amendment to require pharmacists to notify the board of any misdemeanor or felony conviction, or whether any disciplinary action has been taken, as specified, subsequent to the licensee's last renewal.

Amend Section 4403 – Reissuance Without Payment of Fees Prohibited
This section needs amendment to require pharmacy technicians and designated representatives to notify the board of any misdemeanor or felony conviction, or whether any disciplinary action has been taken, as specified, subsequent to the licensee's last renewal.

b. Immunization Proposal – Amendment to Business and Professions Code 4052 and Adoption of 4052.8

Chairperson Graul stated that at the October 2008 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Beginning in November 2007, board staff worked with stakeholders to address questions as well as to elicit support for this proposal for sponsorship in 2008. However, in April 2008, after consideration it was decided not to move the proposal last year due to a lack of staff as well as other legislative priorities.

Board staff is contacting potential authors for this proposal and will resume stakeholder meetings in February 2009 to solidify a broad base of support for this proposal.

Chairperson Graul indicated that a copy of the proposed language as well as a copy of the ACIP Adult and Adolescent Immunization Schedules were provided in the committee meeting materials.

Committee Comments:

Ms. Zinder questioned if the board will be able to find an author in 2009.

Ms. Herold explained why the bill was not pursued last year and highlighted that the board has support from both the California Pharmacists Association as well and the California Retailers Association. Ms. Herold underscored that this proposal is an important public health bill and ensures important training requirements.

Chairperson Graul confirmed that the key to this proposal is to solidify stakeholder support.

Dr. Swart offered to provide contact information of a pharmacist who has experience in community immunizations to assist the board.

c. Elements of a Prescription Label – Amendment to Business and Professions Code section 4076

Chairperson Graul highlighted that at the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a prescription is prescribed, with the "purpose" for which the medicine is prescribed. This change will clarify a pharmacist's authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient, if requested by the patient. This proposal is consistent with the results of the board's prescription label survey where approximately 25% of all respondents requested the purpose of the medicine be included on the label. Purpose removes the owness from the physician to provide the condition.

Committee Comments:

Dr. Swart stated that he was opposed to this proposal at the October 2008 meeting because of concerns with the implementation of such a change. At that time Dr. Swart was concerned that providing the purpose could cause a delay in providing a consumer their prescription because of the current workflow in pharmacies. Dr. Swart requested structuring the requirement to allow for a line on the prescription label where the purpose can be handwritten by the pharmacist.

Ms. Herold responded that the requirement is non-prescriptive, and the pharmacy can determine how to implement the change. She stated further that Dr. Swart's concern can possibly be addressed through the board's efforts to implement SB 472, the standardization of the prescription label. Ms. Herold indicated that staff will confirm this option with legal counsel.

Public Comments:

Steve Gray (Kaiser Permanente and the Pharmacy Foundation of California) stated support for this proposal as it allows for a dialog between the pharmacist and patient. Dr. Gray also stated that as the profession moves forward with electronic prescribing, the law will need to allow for the purpose to be collected as part of the workflow.

Based on a question from the public regarding the actual change in the proposal, Chairperson Graul stated that the purpose can be typed on the label and that if the pharmacist is unclear of the purpose of the medicine, the pharmacist may need to seek clarification from the patient or may need to contact the physician to ascertain the appropriate purpose. Chairperson Graul stated that, ideally, all physicians would provide the purpose of the prescription, however imposing that requirement is outside the scope of the board's jurisdictions.

Ms. Herold amplified why this is such an important consumer protection change.

Amy Gutierrez, representing LA County asked, procedurally, how a change would be reconciled in the event that a condition for which a medicine is prescribed is changed over time.

Ms. Herold responded that the goal is to achieve better patient outcomes.

2. Legislative Proposal Regarding Return to Medicine to Reverse Distributors

Chairperson Graul indicated that this is an action item for the committee to determine if the proposal should be an added item to the legislative calendar for 2009.

Ms. Herold provided background on the proposal, stating that over the last two years, the board has been working with sponsors of drug take back programs to ensure the appropriate disposal of unused medications. Once drugs are aggregated, they are carried back by an integrated waste hauler. Ms Herold highlighted that our law allows a pharmacy to return drugs to a wholesalers only if the drugs are going back into the drug supply, not for destruction. If drugs are to be destroyed or returned for credit, they must be returned via a reverse distributor. The proposed packet defines the criteria for a reverse distributor to perform these functions.

Chairperson Graul discussed each change by code section.

Ms. Zinder asked for clarification on the role of a reverse distributor.

Ms. Herold responded that a reverse distributor will either destroy them via incineration or send them to in antegrated waste hauler for destruction.

Dr. Swart stated that most reverse distributors are disposing of the product.

Dr. Swart suggested that the proposal allows for an estimated quantity in B&PC 4081 (b). Ms. Herold suggested that staff survey some drug manufacturers to identify how they currently determine the quantity.

Ms. Quandt (Longs/CVS) stated concern about the proposed separation of the drugs dispensed to the patient, and later returned because of a prescription error, from those that are never dispensed. Ms. Quandt advocated that in the case where a prescription was erroneously provided to a patient, it could be problematic to arrange for the destruction of the product if is it considered pharmaceutical waste. She sought clarification that a pharmacy that is not participating in the drug take back program would need to contact a reverse distributor directly in order to dispose of any drugs which were a result of a medication error.

Dr. Gray (Kaiser Permanente) suggested that the committee may want to consider a change to 4126.5 (a)(6) to specify who is included in that subsection. Dr. Gray suggested changing the language to include any entity licensed by the board and state

that such a change will help to clarify how such entities are supposed to handle the drugs

MOTION: To recommend to the board the addition of this proposal to amplify regulatory structure of reverse distributors to the board's legislative calendar for 2009.

M/S: AZ/RS

VOTE: 3 OPPOSE: 0 ABSTAIN: 0

3. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

Chairperson Graul provided a brief overview of two legislative proposals that were introduced impacting the practice of pharmacy.

a. AB 67 – Nava

This bill would establish the Pharmacy Patient Protection Act of 2008, which would require pharmacists to dispense all lawfully obtained prescriptions when the prescribed medication is in stock without regard to any ethical, moral, or religious objections.

b. SB 26 – Simitian

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Chairperson Graul indicated that copies of the bills were included in the committee meeting materials. He stated that part of the reason for the legislative overview was to highlight that it is early in the session and, thus, too early to make positions by the committee.

Ms. Zinder agreed that it is early in the session but also expressed concern about AB 67 (Nava)

Ms. Herold indicated that we are uncertain why this proposal is directed at pharmacists.

Dr. Swart stated that AB 69 is written with a broad stroke and would take away a lot of professional judgment by the pharmacist. Dr. Swart state that the board needs to watch this bill as it appears problematic.

Ms. Herold stated that board staff will seek clarification from the author's office on the proposal.

Dr. Gray requested clarification if the proposal (AB 69) nullifies some of the requirements of B&PC 733 and stated that it appears all other provisions within B&PC 733 remain in effect.

Board staff indicated that they will seek clarification from counsel.

4. Public Comment for Items Not on the Agenda

Chairperson Graul reminded the committee that it cannot discuss any of these items.

Dr. Gray requested that the board consider a modification to Health and Safety Code Section 11166 where it makes reference to 11164. Dr Gray state that Section 11164 is no longer relevant and the reference is confusing to pharmacists.

Additionally, Dr. Gray discussed B&PC 4425 which includes a statement that the Department of Health Services (DHS) (now the Department of Health Care Services) is required to provide pharmacies with a poster defining Medi-Cal pricing. Dr. Gray suggested that the board have a discussion with DHS about this requirement as DHS has never provided these posters, and pharmacies are being sued for failure to provide the information as required in B&PC 4425.

A representative from the Drug Policy Alliance (DPDP) provided an overview of the statewide program. She explained that the program is adopted on a county-by-county basis. She indicated that Los Angeles County has the most successful program thus within the state as a result of substantial support and involvement from the pharmacists within the county. Ms Garcia stated that DPDP also takes a proactive role in syringe disposal. She provided the program websites - helpstopaids.com. She thanked the board and the pharmacist community for their continued support. Ms Garcia advised the committee that the DPDP will sunset in 2010 unless they are reauthorized next year to be able continue to provide low-cost access to the pharmacists who depend on the program.

Supervising Inspector Ratcliff recommended that the committee review the requirements in California Code of Regulation section 1707.2 that define the minimum components of patient consultation. Dr. Ratcliff stated that changes to this regulation section may help underscore the importance of the consumer understanding the purpose of a prescribed medicine.

Chairperson Graul requested that all legislative and regulatory proposals be provided in writing to the board for consideration.

The meeting was adjourned at 2:11 p.m.

Attachment D-1

SECOND QUARTERLY REPORT ON LEGISLATION AND REGULATION COMMITTEE GOALS FOR 2008/09

(Text follows next page)

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	1. Secure extension of board's sunset date. *Sept. 30, 2006:* Governor signs **SB 1476** which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008. *June 2007:* **SB 963** (Ridley-Thomas) is amended to alter the sunset review process. *July 2008:* **SB 963** (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments. *Sept. 2008:* Governor signs SB 963 (Chapter 385, Statutes of 2008) 2. Sponsor legislation to update pharmacy law. *Enacted - 1st Qtr. 08/09:* SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions *Oct. 2007:* Board sponsors omnibus provisions for 2008. Four types of changes are discussed. (1) Omnibus changes specific to the PIC and DRC requirements • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4161 – Nonresident wholesaler • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts (2) Omnibus changes to allow for the use of mobile pharmacies • Section 4062 Furnishing Dangerous Drugs During an Emergency. • Section 4110 License Required, Temporary Permit Upon Transfer of Ownership. (3) General omnibus changes • Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions. • Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory • Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy. • Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee. • H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

	(4) Omnibus changes based on recodification of Business and Professions Code section 4052 • *Section 733 – Dispensing Prescription Drugs and Devices* • *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities* • *Section 4040 – Prescription; Content Requirements* • *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist* • *Section 4060 – Controlled Substance – Prescription Required, Exceptions* • *Section 4076 – Prescription Container – Requirements for Labeling* • *Section 4111 – Restrictions on Prescriber Ownership* • *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner* • *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*
Jan. 2008:	*Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill.* *Board approved language for omnibus bill.*
April 2008:	*Some provisions of omnibus bill removed:* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4362 – Entry Into Pharmacists Recovery Program.*
Oct. 2008:	*Governor vetoes SB 1779*
1st Qtr. 08/09:	*Board seeks to pursue omnibus provisions (formerly contained in SB 1779).* *Four areas of change discussed:* *(1) Omnibus changes specific to the PIC and DRC requirements* • *Section 4022.5 – Designated Representative; Designated Representative-in-Charge* • *Section 4036.5 – Pharmacist-in-Charge* • *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action* • *Section 4329 – Nonpharmacists; Prohibited Acts* • *Section 4330 – Proprietors; Prohibited Acts* *(2) Omnibus changes to allow for the use of mobile pharmacies* • *Section 4062 Furnishing Dangerous Drugs During an Emergency.* • *Section 4110 License Required, Temporary Permit Upon Transfer of Ownership.*

	(3) *General omnibus changes* • *Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions.* • *Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory* • *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.* • *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.* *H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.* (4) *Omnibus changes based on recodification of Business and Professions Code section 4052* • *Section 733 – Dispensing Prescription Drugs and Devices* • *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities* • *Section 4040 – Prescription; Content Requirements* • *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist* • *Section 4060 – Controlled Substance – Prescription Required, Exceptions* • *Section 4076 – Prescription Container – Requirements for Labeling* • *Section 4111 – Restrictions on Prescriber Ownership* • *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner* • *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*
	1st Qtr. 08/09: *Board seeks to introduce 2009 omnibus changes (provisions not included in the formber SB 1779):* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4362 – Entry Into Pharmacists Recovery Program.* *New Provisions* • *4200.1 – Pharmacist Examination; Remedial Education* • *4112 – Non-resident Pharmacy: Registration Required* • *4146 – Return and Disposal of Sharps* • *4013 – Subscriber Alert*

3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).

Sept. 30, 2006: *Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.*

4. Secure statutory standards for pharmacies that compound medications (AB 595).

Aug. 2006: *Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.*

5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.

Sept. 2006: *Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.*

Sept. 2008: *Governor signs SB 1307 - which delays implementation of e-pedigree.*

6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.

Oct. 2007: ***Governor signs the following:***

AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.

SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.

SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.

Governor vetoes the following:

AB 249 (Eng) Healing Arts: Settlement Agreements.

AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.

AB 1025 (Bass) Professions and Vocations: Denial of Licensure.

SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.

Oct. 2008: ***Governor signs the following:***

AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks

SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review

Governor vetoes the following:

AB 501 (Swanson) Pharmaceutical Devices

AB 865 (Davis) State Agencies

AB1574 (Plescia) Surgical Clinics: Licensure

Jan. 2009: *Legislation introduced affecting Pharmacy law:*

(New Session) *AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections.*

SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.

7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.

March 2007: *Licensing Committee considers and approves concept. More work is required.*

June 2007: *Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.*

Sept. 2007: *Licensing Committee forwards to full board legislative proposal.*

Oct. 2007: *Board approved draft legislation*

Nov. 2007: *Staff meeting with stakeholders to elicit support for the proposal.*

Dec. 2007: *Staff develop fact sheets and work with experts in immunizations.*

8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.

Oct. 2007: *Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.*

Apr. 2008: *First public forum held in Fremont.*

May 2008: *Staff develop survey form to distribute to consumers to solicit input*
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.

June 2008: *Staff attends community events, interview attendees about prescription label and distribute surveys.*

July 2008: *Staff attends community events, interview attendees about prescription label and distribute surveys.*

Oct. 2008: *Staff continues to attend community events, interview attendees about prescription label and distribute surveys.*
Public Education Committee updated on the status of survey results.

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). *Jan. 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). *Jan. 2007:* *Regulation takes effect following approval by the Office of Administrative Law.* 3. Make technical changes in pharmacy regulations to keep the code updated. *April 2007:* *Section 1775.4 contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.* *June 2007:* *Section 1706.2 - Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.* 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). *March 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 5. Revise and update Disciplinary Guidelines revision and update (section 1760). *Aug. 2006:* *Final changes to Disciplinary Guidelines being compiled by staff.* *Dec. 2006:* *Disciplinary Guidelines is being reformatted into strikeout and underscore version for eventual release for public comment.* *June 2007:* *Enforcement Committee reviews Disciplinary Guidelines and requests additional time to review before being submitted to the board.* *Sept. 2007:* *Enforcement Committee approves Disciplinary Guidelines and recommends board approval.* *Oct. 2007:* *Board approves Disciplinary Guidelines for 45-day comment period.* *Feb. 2008:* *Regulation released for 45 days of public comment.* *April 2008:* *Board Adopts regulation.* *Sept. 2008:* *Rulemaking file submitted for review by the administration.* 6. Self-assessment of a wholesaler by the designated representative (section 1784). *April 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 7. Exempt the address of records of interns from display on the board's Web site (section 1727.1). *Sept. 2006:* *Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.* 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. *July 2006:* *Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.* *June 2007:* *Board staff submit rulemaking file to the California Building Standards Commission.*

9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2).

Feb. 2007: *Board notices regulation for 45 days comment period.*

April 2007: *Board considers comments submitted during public comment period and modifies text regulation to reflect comments.*

May 2007: *New section 1707.2 released for 45 days of public comment.*

July 2007: *Board adopts regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration Review.*

Sept. 2007: *File submitted to the Office of Administrative Law for review.*

Oct. 2007: *Office of Administrative Law approves rulemaking.*

Nov. 2007: *Regulation changes takes effect.*

Nov. 2007: *Staff solicits design submissions from graphic designers.*

Jan. 2008: *Communication and Public Education Committee make recommendations on design submissions.*

Jul. 2008: *Board mails updated Notice to Consumers to all pharmacies in California.*

10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.

Dec. 2007: *Office of Administrative Law approves Section 100 Changes.*

Amend the following:

1707 – Waiver of requirements for off-site storage of records

1709.1 – Designation of pharmacist-in-charge

1715 – Self-assessment of a pharmacy by the pharmacist-in-charge

1717 – Pharmacy practice

1746 – Emergency contraception

1780.1 – Minimum standards for veterinary food-animal drug retailers

1781 – Exemption certificate

1787 – Authorization to distribute dialysis drugs and devices

1790 – Assembling and packaging

1793.8 – Technician check technician

Repeal section 1786 – Exemptions

11. Increase fees to keep the board's contingency fund solvent and maintain operations.

Nov. 2007: *Office of Administrative Law approves rulemaking.*

Nov. 2007: *Staff complete necessary programming changes and begin advising licensees of the change.*

Jan. 1, 2008: *New fees take effect.*

12. Secure regulatory standards for pharmacies that compound.

Dec. 2006: *Licensing Committee evaluates proposed compounding regulations developed in 2004. Some modifications may be needed.*

March 2007: *Licensing Committee convenes discussion of amendments to compounding regulations. More work is required.*

May 2007: *Licensing Committee holds detailed discussion on compounding regulations.*

Sept. 2007: *Licensing Committee forwards regulation proposal to the board for review.*

Nov. 2007: *Board releases language for the 45-day comment period.*

Jan. 2008: *Board held regulation hearing and considers written comments and oral testimony.*

April 2008: *Board votes to withdraw rulemaking.*

Aug. 2008: *Board releases new language for the 45-day comment period.*

	13. Establish an ethics course. *April 2007:* *Board establishes a subcommittee to examine the development of an ethics course.* *Oct. 2007:* *Board votes to pursue regulation change to establish program components.* *Sept. 2008:* *Board notices regulation for 45-day comment period.* *Oct. 2008:* *Board votes to pursue 15-day comment period and, absent any negative comments, authorizes the Executive Officer to complete the rulemaking file.*

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	1. Initiate review of the pharmacist-in-charge requirement. ***Aug. 2007:*** *Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.* ***Oct. 2007:*** *Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.* ***Jan. 2008:*** *Board approves omnibus language recommended by Legislation and Regulation Committee.* • *Section 4022.5 – Designated Representative; Designated Representative-in-Charge* • *Section 4036.5 – Pharmacist-in-Charge* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action* • *Section 4329 – Nonpharmacists; Prohibited Acts* • *Section 4330 – Proprietors; Prohibited Acts* ***April 2008:*** *The following provisions are not incorporated into omnibus bill.* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* ***Sept. 2008:*** *Governor vetoes SB 1779.* ***Jan. 2009:*** *Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill.*